RD2008-07

Registration Decision

Spirotetramat

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Overview

Registration Decision for Spirotetramat

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of Spirotetramat Technical Insecticide, Movento 150 OD Insecticide and Movento 240 SC Insecticide containing the technical grade active ingredient spirotetramat to control a variety of insect pests on field vegetable crops, tree fruits, hops, grapes (excluding table grapes) and small fruit vine crops.

An evaluation of available scientific information found that, under the conditions of use, the products have value and do not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document[1]: Proposed Registration Decision PRD2008-07, *Spirotetramat*. This Registration Decision[2] describes this stage of the PMRA's regulatory process for spirotetramat and summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2008-07. This decision is consistent with the proposed registration decision stated in PRD2008-07.

For more details on the information presented in this Registration Decision, please refer to the Proposed Registration Decision PRD2008-07, *Spirotetramat*, which contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration[3]. The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

3 "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act*.

4 "Value" as defined by subsection 2(1) of *Pest Control Products Act*"...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (a) efficacy; (b) effect on host organisms in connection with which it is intended to be used; and (c) health, safety and environmental benefits and social and economic impact."

To reach its decisions, the PMRA applies hazard and risk assessment methods as well as policies that are rigorous and modern. These methods consider the unique characteristics of sensitive subpopulations in humans (e.g. children) and organisms in the environment (e.g. those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties present when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the PMRA's website at www.pmra-arla.gc.ca.

What is Spirotetramat?

Spirotetramat is an insecticide applied directly onto the leaves of plants for the control of sucking pests such as mites and aphids. It is applied to a variety of crops, including fruits and vegetables. Spirotetramat inhibits lipid biosynthesis in target insects and is most effective against immature insect life stages.

Health Considerations

Can Approved Uses of Spirotetramat Affect Human Health?

Spirotetramat is unlikely to affect your health when Movento 150 OD Insecticide and Movento 240 SC Insecticide are used according to label directions.

Potential exposure to spirotetramat may occur through the diet (food and water) or when handling and applying the product. When assessing health risks, two key factors are considered: the levels where no health effects occur in animal testing and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (e.g. children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. The health effects noted in animals occur at doses more than 100 times higher (and often much higher) than levels to which humans are normally exposed when spirotetramat products are used according to label directions.

Spirotetramat Technical Insecticide was moderately irritating to the eyes and was a dermal sensitizer in animals. Consequently, the statements "Warning—Eye Irritant" and "Potential Skin Sensitizer" are required on the label. End-use product Movento 150 OD Insecticide was considered to be of slight acute systemic toxicity, was severely irritating to the eyes and was a dermal sensitizer in animals. For these reasons, the statements "Danger—Eye Irritant", "Potential Skin Sensitizer" and "Poison" (accompanied by the appropriate symbol) are required on the label. End-use product Movento 240 SC Insecticide was a dermal sensitizer in animals, thus requiring the label statement "Potential Skin Sensitizer".

Spirotetramat did not cause cancer in animals and was not genotoxic. Spirotetramat did cause neurotoxic effects following acute exposure in the rat and repeat dosing in the dog. The male reproductive system (testis and sperm) was also targeted in the rat at high doses. The first signs of toxicity in animals given daily doses of spirotetramat over longer periods of time were decreases in thyroxine (T4), decreased thymus size with increased incidence of thymus involution and dilatation of the cerebral brain ventricles in dogs. The risk assessment protects against these effects by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests.

When spirotetramat was given to pregnant animals, effects on the developing fetus were observed at doses that were toxic to the mother, indicating that the fetus is not more sensitive to spirotetramat than the adult animal. In light of uncertainty with regards to whether the alterations in thyroid hormones and brain effects observed in adult animals could translate into adverse effects on the developing fetus, extra protective measures were applied during the risk assessment to further reduce the allowable level of human exposure to spirotetramat.

Residues in Water and Food

Dietary risks from food and water are not of concern

Refined aggregate dietary intake estimates (food plus water) revealed that the general population and children, the subpopulation that would ingest the most spirotetramat relative to body weight, are expected to be exposed to less than 20.5% of the acceptable daily intake. Based on these estimates, the chronic dietary risk from exposure to spirotetramat residues is not of concern for any of the population subgroups.

A single dose of spirotetramat is not likely to cause acute health effects in the general population (including infants and children). An aggregate (food and water) dietary exposure estimate of 1.1% of the acute reference dose is not considered to be a health concern for any of the population subgroups.

The *Food and Drugs Act* prohibits the sale of adulterated food, that is, food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established under the authority of the *Food and Drugs Act* through the evaluation of scientific data under the *Pest Control Products Act*. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Residue trials conducted in representative NAFTA geographical locations on various crops using end-use products containing spirotetramat were acceptable. The residue trials were conducted in or on potatoes (Crop Subgroup 1C), grapes (Crop Subgroup 13-07F), Brassica vegetables (Crop Subgroups 5A and 5B), cucurbits (Crop Group 9), leafy vegetables, except Brassica (Crop Group 4), fruiting vegetables (Crop Group 8), hops, pome fruits (Crop Group 11), stone fruits (Crop Group 12) and tree nuts (Crop Group 14). Residue data from European residue trials on dry bulb onions and strawberries, as well as citrus (Crop Group 10) from representative NAFTA geographical locations are sufficient to establish the proposed import maximum residue limits. The MRLs for this active ingredient can be found in the Science Evaluation of PRD2008-07.

Occupational Risks From Handling Movento 150 OD Insecticide and Movento 240 SC Insecticide.

Occupational risks are not of concern when Movento 150 OD Insecticide and Movento 240 SC Insecticide are used according to label directions, which include protective measures.

Farmers and pesticide applicators mixing, loading or applying Movento 150 OD Insecticide and Movento 240 SC Insecticide as well as field workers re-entering freshly treated fields can come in direct contact with Movento 150 OD Insecticide and Movento 240 SC Insecticide on the skin or through inhalation of spray mists. Therefore, the label will specify that anyone mixing or loading Movento 150 OD Insecticide and Movento 240 SC Insecticide must wear a long-sleeved shirt, pants and chemical-resistant gloves and that anyone applying the product must wear a long-sleeved shirt and pants. Taking into consideration these label requirements and that occupational exposure is expected to be short-term because this insecticide is applied only a couple of times per year, risk to farmers, applicators or workers is not a concern.

For bystanders, exposure is expected to be much less than that of field workers and is considered negligible. Therefore, health risks to bystanders are not of concern.

For people who enter treated fields for "pick-your-own" activities, exposure is expected to be short-term since this activity normally only happens once per year. Taking into consideration the label requirements, the risk to people that enter treated fields to pick produce is not a concern.

Environmental Considerations

What Happens When Spirotetramat Is Introduced Into the Environment?

Environmental risks are not of concern when Movento 150 OD Insecticide and Movento 240 SC Insecticide are used according to label directions, which include precautionary label statements and buffer zones.

Spirotetramat is non-persistent in soil and in water, with biotransformation being an important route of transformation. In aquatic systems under alkaline conditions, hydrolysis and phototransformation may also contribute to the dissipation of spirotetramat. Based on the physical and chemical properties of spirotetramat, it is not expected that this compound will leach through the soil profile and contaminate groundwater. Major transformation products in soil and water have been identified and are discussed in the Science Evaluation of PRD2008-07. Residues of spirotetramat are not expected to be present in air due to its low volatility.

Use of spirotetramat does not present a risk to earthworms, small mammals, birds or aquatic organisms. However, spirotetramat may pose a risk to honeybee broods, beneficial arthropods and non-target plants. Precautionary label statements are thus included on the label and buffer zones of one to two metres are required to mitigate exposure of sensitive terrestrial habitats from spray drift.

Value Considerations

What Is the Value of Movento 150 OD Insecticide and Movento 240 SC Insecticide?

Movento 150 OD Insecticide and Movento 240 SC Insecticide control a variety of pests and can be used on a broad range of crop groups.

A single application of Movento 150 OD Insecticide or Movento 240 SC Insecticide provides control or suppression of a range of insect pests on a variety of fruit and vegetable crops. Use of this insecticide is compatible with current management practices and conventional crop production systems, and users are familiar with monitoring techniques to determine if and when applications are needed.

Other insecticides from the same class as spirotetramat are currently registered for use on some of the same crops as on the Movento labels; however, spirotetramat controls different pests and can be used on a broader range of crop groups. Prudent use of insecticides in this class should be observed to prevent the development of resistance. When applied according to label directions, Movento 150 OD Insecticide and Movento 240 SC Insecticide are effective in controlling whiteflies, mealybugs, some species of aphids, phylloxera, pear psylla, psyllids, San Jose scale, Lecanium scale (suppression only) and white peach scale.

Measures to Minimize Risk

Registered pesticide product labels include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures on the labels of Movento 150 OD Insecticide and Movento 240 SC Insecticide to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

- **Human Health**
  As there is a concern with users coming into direct contact with spirotetramat on the skin or inhaling spray mists, anyone mixing/loading and involved in clean-up or repair activities with Movento 150 OD Insecticide and Movento 240 SC Insecticide must wear a long-sleeved shirt, pants and chemical-resistant gloves. In addition, anyone applying the products must wear a long-sleeved shirt and pants.

- **Environment**
  To protect bees and beneficial arthropods, precautionary statements are included on the Movento 150 OD Insecticide and Movento 240 SC Insecticide labels. To protect non-target terrestrial plants, Movento 150 OD Insecticide and Movento 240 SC Insecticide cannot be sprayed within one to two metres of sensitive terrestrial habitats. The distance allowed depends on the type of spray equipment used and the timing of application.

Other Information

1. The relevant test data on which the decision is based (as referenced in this document) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra_inforserv@hc-sc.gc.ca).

2. Any person may file a notice of objection[5] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the PMRA's website (Requesting a Reconsideration of Decision, www.pmra-arla.gc.ca/english/pubreg/reconsideration-e.html) or contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra_inforserv@hc-sc.gc.ca).

[5] As per subsection 35(1) of the *Pest Control Products Act*.

References

A. LIST OF STUDIES/INFORMATION SUBMITTED BY REGISTRANT

1.0 Chemistry

Spirotetramat Technical Insecticide

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1314090	2004, Validation of HPLC-method AM002104MF1 - Determination of BYI 08330 in Formulations -, VB1-AM002104MF1, DACO: 2.13.1
1314096	2004, Spirotetramat (BYI08330) - Assay of Technical Grade Active Ingredient - HPLC - External Standard, AM001104MP1, DACO: 2.13.1
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1314108	1999, Analytical procedure for the Karl Fischer water determination, 2005-0009701-99, DACO: 2.13.4 CBI
1314112	2004, BYI 08330, Mix-Batch 08045/0003 - Melting point, boiling point, thermal stability, 20040156.01, DACO: 2.14.4,2.14.5
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1314114	2004, BYI 08330 (AE 1302943) - Surface tension, PA03/065, DACO: 2.14.2
1314119	2003, BYI 08330 (AE 1302943) - Physical characteristics color, appearance and odor, PA03/035, DACO: 2.14.1,2.14.3
1314121	2003, BYI 08330 (AE 1302943) - Partition coefficient 1-octanol/water (HPLC-method), PA03/036, DACO: 2.14.11
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1314236	2006, BYI 08330 (Spirotetramat); Substance, technical - Explosive properties A.14., 20060305.02, DACO: 2.16

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1314238	2006, BYI 08330 (Spirotetramat); Substance, technical - Oxidizing properties A.17, 20060305.04, DACO: 2.16
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1314240	2006, Surface tension of BYI 08330 - Technical substance, PA06/024, DACO: 2.16
1314241	2006, Relative density of BYI 08330 - Technical substance, PA06/025, DACO: 2.14.6
1314242	2006, The oxidation or reduction properties of BYI 08330 - Technical substance, PA06/027, DACO: 2.16
1314252	2005, BYI 08330 (AE 1302943) - Determination of the dissociation constant, M-261598-01-1, DACO: 2.14.10
1314267	2006, Physical characteristics - Color, physical state and odor of BYI 08330 - Technical substance, PA06/026, DACO: 2.14.1,2.14.3
1314268	2006, Water solubility of BYI 08330 (AE 1302943) in distilled water (Flask Method), PA06/033, DACO: 2.14.7
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1314425	2006, BYI 08330 - Technical material - discussion of the formation of impurities, M-274943-01-1, DACO: 2.11.4,2.12.2 CBI
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1314434	2006, Analysis of two batches NLL 6425-9 and SAV 5505-085/2, Spirotetramat (BYI 08330), 15-810-2302, DACO: 2.13.3 CBI
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1314547	2006, Tier 2 summary of the analytical methods and validation for Spirotetramat (BYI 08330) - Confidential information, M-275688-01-1, DACO: 2.13.1 CBI
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Movento® 240 SC Insecticide

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1314193	2005, Determination of safety-relevant data of BYI 08330 SC 240. Further Code Name: Spirotetramat SC 240, 05/01281, DACO: 3.5.11,3.5.12,3.5.8
1314209	2006, Validation of HPLC-method AM002104MF1 - Determination of Spirotetramat in Formulations, VS3.1-AM002104MF1, DACO: 3.4.1
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Movento® 150 OD Insecticide

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PMRA Document Number	Reference
1314250	2005, Validation of HPLC-method AM002104MF1 - determination of BYI 08330 in formulations -, VB2-AM002104MF1, DACO: 3.4.1
1314364	2006, Safety relevant technical properties of BYI 08330 oil dispersion 150 g/litre - Recipe Code: 30-00364846 - Material number: 06424376 - Batch code: 08030/0233(0152), FOR0842(PC)01, DACO: 3.5.11,3.5.12,3.5.8
1314449	2006, Independent laboratory validation of analytical method 00836 for the determination of BYI 08330 and BYI 08330-enol in drinking and surface water by HPLC-MS/MS and HPLC-UV, RAFNX019, MRID: 469044-93, DACO: 3.7,5.14,7.8,8.6
1314549	2006, Tier 2 summary of the identity of the plant protection product for Spirotetramat (BYI 08330) OD 150, M-275699-01-1, DACO: 3.7
1314550	2006, Tier 2 summary of the physical, chemical and technical properties of the plant protection product for Spirotetramat (BYI 08330) OD 150, M-275702-01-1, DACO: 3.5
1314611	2006, Reference list of the physical, chemical and technical properties of on the plant protection product Spirotetramat 150 g/L OD Material No.: 06424376 sorted by Annex points, M-277289-01-1, DACO: 3.5.1,3.5.2,3.5.3
1314615	2006, Product chemistry of Movento 150 OD insecticide, BR2531, MRID: 469044-03C, DACO: 3.0 CBI
1314620	2006, Independent laboratory validation of method FN-002-S05-02 for the determination of BYI08330 and its metabolites BYI08330-enol, BYI08330-keto-hydroxy and BYI08330-MA-amide in soil and sediment by LC/MS/MS, MR-06/037, MRID: 469044-15, DACO: 3.7,5.14
1314740	2006, Tier 2 summary of the identity of the plant protection product for Spirotetramat (BYI 08330) OD 150 - Confidential information, M-275693-02-1, DACO: 3.7 CBI
1314777	2006, Tier 2 summary of the identity of the plant protection product for Spirotetramat (BYI 08330) OD 150, M-275699-01-1, DACO: 3.7
1314778	2006, Tier 2 summary of the physical, chemical and technical properties of the plant protection product for Spirotetramat (BYI 08330) OD 150, M-275702-01-1, DACO: 3.7
1314803	2006, Reference list of the physical, chemical and technical properties of on the plant protection product Spirotetramat 150 g/L OD Material No.: 06424376 sorted by Annex points, M-277289-01-1, DACO: 3.5.1,3.5.2,3.5.3

2.0 Impact on Human and Animal Health

PMRA Document Number	Reference
1314092	2004, An acute oral LD50 study in the rat with BYI 08330, 200398, MRID: 469045-27, DACO: 4.2.1
1314138	2005, Technical grade BYI 08330: A subchronic toxicity testing study in the rat, 201136, MRID: 469045-38, DACO: 4.3.1
1314139	2004, Technical grade BYI 08330: A subacute toxicity feeding study in the Beagle dog, 201012, MRID: 469045-72, DACO: 4.3.3
1314154	2005, Technical grade BYI 08330 - A 90-day subchronic toxicity feeding study in the Beagle dog, 201223, MRID: 469045-41, DACO: 4.3.2
1314156	2005, An acute oral neurotoxicity screening study with technical grade BYI 08330 in Wistar Rats, 201283, MRID: 469045-60, DACO: 4.5.12
1314160	2006, BYI 08330-mono-hydroxy (Project: BYI 08330) - Salmonella/microsome test - Plate incorporation and preincubation method, AT02716, MRID: 469046-04, DACO: 4.8
1314161	2006, BYI 08330 150 OD - Acute skin irritation/corrosion on rabbits, AT02359, MRID: 469045-80, DACO: 4.6.5
1314162	2006, Chromosome aberration assay in bone marrow cells of the mouse with BYI 08330, AR00070, MRID: 469045-58, DACO: 4.5.7
1314185	2006, BYI 08330 - Study for the skin sensitization effect in guinea pigs (guinea pig maximization test according to Magnusson and Kligman), 32273, MRID: 469045-33, DACO: 4.2.6
1314211	2005, Acute eye irritation study of BYI 08330 by instillation into the conjunctival sac of rabbits, R8146, MRID: 469045-31, DACO: 4.2.4
1314212	2006, BYI 08330 150 OD - Acute eye irritation on rabbits, AT02358, MRID: 469045-79, DACO: 4.6.4
1314213	2002, Acute skin irritation test (patch test) of BYI 8330 in rabbits, R8147, MRID: 469045-32, DACO: 4.2.5
1314214	2002, BYI 08330 - Micronucleus-test on the male mouse, AT00048, MRID: 469045-56, DACO: 4.5.7
1314215	2003, BYI 08330 - Unscheduled DNA synthesis test with rat liver cells in vivo, AT00526, MRID: 469045-57, DACO: 4.5.8
1314216	2004, BYI 08330 - Study for the skin sensitization effect in guinea pigs (Buehler Patch test), AT01317, MRID: 469045-34, DACO: 4.2.6
1314217	2002, BYI 08330 - Salmonella/microsome test plate incorporation and preincubation method, AT00056, MRID: 469045-52, DACO: 4.5.4
1314218	2005, BYI 08330 150 OD (Project: BYI 08330) - Study for the skin sensitization effect in guinea pigs (Buehler patch test), AT01873, MRID: 469045-82, DACO: 4.6.6

PMRA Document Number	Reference
1314219	2005, BYI 08330 150 OD - Acute toxicity in the rat after oral administration, AT02161, MRID: 469045-76, DACO: 4.6.1
1314220	2005, BYI 08330 240 SC - Acute toxicity in the rat after oral administration, AT02162, MRID: 469045-85, DACO: 4.6.1
1314221	2005, BYI 08330 150 OD - Acute toxicity in the rat after dermal application, AT02164, MRID: 469045-77, DACO: 4.6.2
1314222	2005, BYI 08330 240 SC - Acute toxicity in the rat after dermal application, AT02165, MRID: 469045-86, DACO: 4.6.2
1314223	2005, BYI 08330 240 SC - Acute eye irritation on rabbits, AT02290, MRID: 469045-88, DACO: 4.6.4
1314225	2004, BYI 08330 - Developmental toxicity study in rabbits after oral administration, AT01003 (Study No. T 3063167), MRID: 469045-44, DACO: 4.5.3
1314228	2004, An acute dermal LD50 study in the rat with BYI 08330, 200399, MRID: 469045-29, DACO: 4.2.2
1314245	2005, Technical grade BYI 08330 (common name Spirotetramat): a chronic toxicity testing study in the rat, 201285, MRID: 469045-47, DACO: 4.4.1
1314272	2005, BYI 08330, Synonym: FHN 08330 - Developmental toxicity study in rats after oral administration, AT01413, MRID: 469045-43, DACO: 4.5.2
1314278	2006, BYI 08330 240 SC - Acute skin irritation/corrosion on rabbits, AT02291, MRID: 469045-89, DACO: 4.6.5
1314279	2006, BYI 08330 - Synonym: FHN 08330 - Supplementary developmental toxicity study in rats after oral administration, AT01512, MRID: 469045-45, DACO: 4.5.2
1314281	2006, BYI 08330 240 SC (Project: BYI 08330) - Study for the skin sensitization effect in guinea pigs (Buehler patch test), AT01876, MRID: 469045-90, DACO: 4.6.6
1314282	2006, BYI 08330 150 OD - Acute inhalation toxicity in rats, AT02396, MRID: 469045-78, DACO: 4.6.3
1314283	2006, BYI 08330-CIS-Ketohydroxy - Acute toxicity in the rat after oral administration, AT02506, MRID: 469045-93, DACO: 4.6.1
1314284	2006, BYI 08330 150 OD ready to use dilution (Project: BYI 08330) - Study for the skin sensitization effect in guinea pigs (Buehler patch test), AT02570, MRID: 469045-81, DACO: 4.6.6
1314285	2006, BYI 08330-desmethyl-ketohydroxy - Acute toxicity in the rat after oral administration, AT02927, MRID: 469045-96, DACO: 4.6.1

PMRA Document Number	Reference
1314291	2006, [Azaspirodecenyl-3-14C]BYI 08330: Distribution of the total radioactivity in male and female rats determined by quantitative whole body autoradiography (QWBA) including determination of the total radioactivity in excreta and exhaled 14CO2, MEF-06/15
1314294	2006, BYI 08330 - Evaluation of potential dermal sensitization in the local lymph node assay, SA 04120, MRID: 469045-65, DACO: 4.2.6
1314296	2006, BYI 08330 240 SC ready to use dilution (Project: BYI 08330) - Study for the skin sensitization effect in guinea pigs (Buehler patch test), AT02598, MRID: 469045-91, DACO: 4.6.6
1314297	2006, BYI 08330 240 SC - Acute inhalation toxicity in rats, AT02374, MRID: 469045-87, DACO: 4.6.3
1314311	2006, [Azaspirodecenyl-3-14C]BYI 08330-enol-glucoside supplemental study: adsorption, distribution, excretion and metabolism in the rat, MEF-06/006, MRID: 469046-02, DACO: 4.5.9
1314318	2006, BYI 08330 - Cytogenetic screening with chinese hamster V79 cells, AT00194, MRID: 469045-55, DACO: 4.5.6
1314327	2006, Technical grade BYI 08330 (common name Spirotetramat): An oncogenicity testing study in the rat, 201358, MRID: 469045-49, DACO: 4.4.2
1314329	2006, BYI 08330-desmethyl-ketohydroxy (Project: BYI 08330) - Salmonella/microsome test - Plate incorporation and preincubation method, AT03027, MRID: 469045-97, DACO: 4.8
1314330	2006, BYI 08330-di-hydroxy (Project: BYI 08330) - Salmonella/microsome test - Plate incorporation and preincubation method, AT03069, MRID: 469045-99, DACO: 4.8
1314331	2006, BYI 08330 - Salmonella/microsome test - Plate incorporation and preincubation method, AT03070, MRID: 469045-51, DACO: 4.5.4
1314337	2006, BYI 08330-Enol - Investigation of the testicular/sperm toxicity in the rat following 21 days of exposure by gavage, SA06011, DACO: 4.8
1314341	2006, BYI 08330 - In vitro chromosome aberration test with chinese hamster V79 cells, AT00055, MRID: 469045-54, DACO: 4.5.6
1314367	2005, Technical grade BYI 08330: A subchronic toxicity testing study in the mouse, 201284, MRID: 469045-39, DACO: 4.3.1
1314378	G.D. Cappon, T.L. Fleeman, R.E. Chapin, and M.E. Hurtt, 2005, Effects of feed restriction during organogenesis on embryo-fetal development in rabbit, Birth Defects Research Part B: Developmental and Reproductive Toxicology: 44(5) 424-430. DACO: 4.4.5
1314381	2006, Validation of the Buehler Patch Test Mehod used by the Health Care Toxicology of Bayer HealthCareAG, performed in guinea pigs of the strain Crl:HA with Alpha Hexyl Cinnamic Aldehyde, AT01212, MRID: 469045-35, DACO: 4.6.6

PMRA Document Number	Reference
1314382	2006, BYI 08330 - V79/HPRT-test in vitro for the detection of induced forward mutations, AT00137A, MRID: 469045-53, DACO: 4.5.5
1314413	2005, A homogeneity and stability study of BYI 08330 technical in rodent ration, 201297, MRID: 469045-73, DACO: 4.6.8,4.7.7,5.14
1314422	2004, A liquid chromatographic method for the determination of BYI 08330 in rodent ration, 200423, MRID: 469045-75, DACO: 4.6.8,4.7.7,5.14
1314427	2006, BYI 08330-di-hydroxy - Acute toxicity in the rat after oral administration, AT02995, MRID: 469045-98, DACO: 4.2.9
1314428	2006, A chronic toxicity feeding study in the beagle dog with technical grade BYI 08330, 201486, MRID: 469045-48, DACO: 4.3.2
1314433	2006, BYI 08330 (Spirotetramat) - Assessment of literature research in various databases, M-275046-01-1, DACO: 4.8
1314438	2006, BYI 08330 - Pilot study on developmental toxicity in rats after oral administration, T3068559, MRID: 469045-59, DACO: 4.5.2
1314466	2006, A subacute dermal toxicity study in rats with BYI 08330, 201505, MRID: 469045-42, DACO: 4.3.5
1314474	2006, BYI 08330-mono-hydroxy - Acute toxicity in the rat after oral administration, AT02687, MRID: 469046-03, DACO: 4.2.9
1314476	2006, BYI 08330 - Evaluation of the potential reproductive toxicity in the male rat following daily oral administration by gavage, SA 04181, MRID: 469045-69, DACO: 4.8
1314542	2006, Technical grade BYI 08330 (common name Spirotetramat): A two generation reproductive toxicity study in the Wistar rat, 201426-1, MRID: 469045-46, DACO: 4.5.1
1314554	2006, Cyclic ketoenols BSN 3457, BSN 2342, FHN 7504, FHN 8330 - Subacute exploratory toxicity studies in rats (application by feed over 4 weeks), T0061869, MRID: 469045-37, DACO: 4.3.3
1314555	2006, Technical grade BYI 08330 - A dose range-finding reproductive toxicity study in the Wistar rat (revised report), 201300-1, MRID: 469045-71, DACO: 4.5.1
1314557	2006, BYI 08330 (c.n.: --) - Study on acute inhalation toxicity in rats according to OECD no. 403, 32020, MRID: 469045-30, DACO: 4.2.3
1314558	2006, Physiology based pharmacokinetic simulation of BYI 08330 in male rats, BTS-WSM0602, MRID: 469045-67, DACO: 4.5.9
1314560	2006, BYI 08330-Enol: Exploratory 10-day toxicity study in the rat by gavage, M-274171-01-2, MRID: 469046-01, DACO: 4.3.8
1314563	2006, BYI 08330 - Pilot developmental toxicity study in rabbits after oral administration, T3062735, MRID: 469045-70, DACO: 4.5.3

PMRA Document Number	Reference
1314584	2006, BYI 08330 - Subacute study with mice (keto-enol design), T2070951, MRID: 469045-36, DACO: 4.3.3
1314585	2006, [Azaspirodecenyl-3-14C]-BYI 08330: Comparison of the in vitro metabolism in liverbeads from male rat, mouse and human, SA05319, MRID: 469045-66, DACO: 4.5.9
1314632	2006, [Azaspirodecane-3-14C]BYI 08330-ketohydroxy: Adsorption, distribution, excretion and metabolism in the rat, MEF-06/007, MRID: 469045-95, DACO: 4.5.9
1314635	2006, PBPK-Simulation of BYI 08330 in male rats at high doses, BTS-WSM0603-1, MRID: 469045-68, DACO: 4.5.9
1314686	2006, Tier 1 summary of the toxicological studies and exposure data and information on the plant protection product Spirotetramat 150 g/L OD - Material No.: 06424376, M-277320-03-1, DACO: 4.1,5.1
1314691	2006, [Azaspirodecenyl-3-14C]BYI 08330: Adsorption, distribution, excretion and metabolism in the rat, MEF-048/04, MRID: 469045-04, DACO: 4.5.9
1314693	2006, Tier 2 summary of the toxicological and toxicokinetic studies on the active substance for Spirotetramat (BYI 08330), M-277720-02-1, DACO: 4.1
1314717	2006, Tier 2 summary of the toxicological studies and exposure data and information on the plant protection product Spirotetramat 150 g/L OD , material no. 06424376, M-278141-01-1, DACO: 4.1,5.1
1314718	2006, Tier 2 summary of the toxicological studies and exposure data and information on the plant protection product for Spirotetramat 240 SC - Material No. 06 424 384, M-278143-01-1, DACO: 4.1,5.1
1314721	2006, Revised report : Technical grade BYI 08330 (common name Spirotetramat): An oncogenicity testing study in the mouse, 201359-1, MRID: 469045-50, DACO: 4.4.3
1314723	2005, A revised homogeneity and stability study of BYI 08330 technical in rodent ration, 201363, MRID: 469045-74, DACO: 4.4.3
1314725	2006, Tier 1 summary of the toxicological and toxicokinetic studies on the active substance - Spirotetramat (BYI08330), M-277522-03-1, DACO: 4.1
1314738	2005, Technical grade BYI 08330 (common name Spirotetramat): a chronic toxicity testing study in the rat, 201285, MRID: 469045-47, DACO: 4.4.1
1314831	2006, Tier 1 summary of the toxicological studies and exposure data and information on the plant protection product Spirotetramat 150 g/L OD - Material No.: 06424376, M-277320-03-1, DACO: 4.1
1314833	2006, Tier 2 summary of the toxicological and toxicokinetic studies on the active substance for Spirotetramat (BYI 08330), M-277720-02-1, DACO: 4.1

PMRA Document Number	Reference
1314846	2006, Tier 2 summary of the toxicological studies and exposure data and information on the plant protection product Spirotetramat 150 g/L OD , material no. 06424376, M-278141-01-1, DACO: 4.1,5.1
1314847	2006, Tier 2 summary of the toxicological studies and exposure data and information on the plant protection product for Spirotetramat 240 SC - Material No. 06 424 384, M-278143-01-1, DACO: 4.1,5.1
1314851	2006, Tier 1 summary of the toxicological and toxicokinetic studies on the active substance - Spirotetramat (BYI08330), M-277522-03-1, DACO: 4.1
1314220	2005, BYI 08330 240 SC - Acute toxicity in the rat after oral administration, AT02162, MRID: 469045-85, DACO: 4.6.1
1314222	2005, BYI 08330 240 SC - Acute toxicity in the rat after dermal application, AT02165, MRID: 469045-86, DACO: 4.6.2
1314223	2005, BYI 08330 240 SC - Acute eye irritation on rabbits, AT02290, MRID: 469045-88, DACO: 4.6.4
1314278	2006, BYI 08330 240 SC - Acute skin irritation/corrosion on rabbits, AT02291, MRID: 469045-89, DACO: 4.6.5
1314281	2006, BYI 08330 240 SC (Project: BYI 08330) - Study for the skin sensitization effect in guinea pigs (Buehler patch test), AT01876, MRID: 469045-90, DACO: 4.6.6
1314296	2006, BYI 08330 240 SC ready to use dilution (Project: BYI 08330) - Study for the skin sensitization effect in guinea pigs (Buehler patch test), AT02598, MRID: 469045-91, DACO: 4.6.6
1314297	2006, BYI 08330 240 SC - Acute inhalation toxicity in rats, AT02374, MRID: 469045-87, DACO: 4.6.3
1314686	2006, Tier 1 summary of the toxicological studies and exposure data and information on the plant protection product Spirotetramat 150 g/L OD - Material No.: 06424376, M-277320-03-1, DACO: 4.1,5.1
1314717	2006, Tier 2 summary of the toxicological studies and exposure data and information on the plant protection product Spirotetramat 150 g/L OD , material no. 06424376, M-278141-01-1, DACO: 4.1,5.1
1314718	2006, Tier 2 summary of the toxicological studies and exposure data and information on the plant protection product for Spirotetramat 240 SC - Material No. 06 424 384, M-278143-01-1, DACO: 4.1,5.1
1314831	2006, Tier 1 summary of the toxicological studies and exposure data and information on the plant protection product Spirotetramat 150 g/L OD - Material No.: 06424376, M-277320-03-1, DACO: 4.1
1314846	2006, Tier 2 summary of the toxicological studies and exposure data and information on the plant protection product Spirotetramat 150 g/L OD , material no. 06424376, M-278141-01-1, DACO: 4.1,5.1

PMRA Document Number	Reference
1314847	2006, Tier 2 summary of the toxicological studies and exposure data and information on the plant protection product for Spirotetramat 240 SC - Material No. 06 424 384, M-278143-01-1, DACO: 4.1,5.1
1314161	2006, BYI 08330 150 OD - Acute skin irritation/corrosion on rabbits, AT02359, MRID: 469045-80, DACO: 4.6.5
1314212	2006, BYI 08330 150 OD - Acute eye irritation on rabbits, AT02358, MRID: 469045-79, DACO: 4.6.4
1314218	2005, BYI 08330 150 OD (Project: BYI 08330) - Study for the skin sensitization effect in guinea pigs (Buehler patch test), AT01873, MRID: 469045-82, DACO: 4.6.6
1314219	2005, BYI 08330 150 OD - Acute toxicity in the rat after oral administration, AT02161, MRID: 469045-76, DACO: 4.6.1
1314221	2005, BYI 08330 150 OD - Acute toxicity in the rat after dermal application, AT02164, MRID: 469045-77, DACO: 4.6.2
1314282	2006, BYI 08330 150 OD - Acute inhalation toxicity in rats, AT02396, MRID: 469045-78, DACO: 4.6.3
1314284	2006, BYI 08330 150 OD ready to use dilution (Project: BYI 08330) - Study for the skin sensitization effect in guinea pigs (Buehler patch test), AT02570, MRID: 469045-81, DACO: 4.6.6
1314686	2006, Tier 1 summary of the toxicological studies and exposure data and information on the plant protection product Spirotetramat 150 g/L OD - Material No.: 06424376, M-277320-03-1, DACO: 4.1,5.1
1314717	2006, Tier 2 summary of the toxicological studies and exposure data and information on the plant protection product Spirotetramat 150 g/L OD , material no. 06424376, M-278141-01-1, DACO: 4.1,5.1
1314725	2006, Tier 1 summary of the toxicological and toxicokinetic studies on the active substance - Spirotetramat (BYI08330), M-277522-03-1, DACO: 4.1
1314831	2006, Tier 1 summary of the toxicological studies and exposure data and information on the plant protection product Spirotetramat 150 g/L OD - Material No.: 06424376, M-277320-03-1, DACO: 4.1
1314846	2006, Tier 2 summary of the toxicological studies and exposure data and information on the plant protection product Spirotetramat 150 g/L OD , material no. 06424376, M-278141-01-1, DACO: 4.1,5.1
1314851	2006, Tier 1 summary of the toxicological and toxicokinetic studies on the active substance - Spirotetramat (BYI08330), M-277522-03-1, DACO: 4.1
1314123	2004, Degradation of [azaspirodecenyl-3-^{14}C]BYI08330 by plant suspension cell cultures (supplemental study to metabolism in plants), MEF-262/03 (and Study No. M1711274-3), DACO: 6.3

PMRA Document Number	Reference
1314182	2006, Enforcement method 00888 for the determination of residues of BYI 08330 and BYI08330-enol in/on plant material by HPLC-MS/MS, MR-102/04 (and Method No. 00888), DACO: 7.2.1,7.2.4
1314184	2006, Metabolism of [azaspirodecenyl-3-14C]BYI08330 in lettuce, MEF-049/04 (and Study No. M1731301-6), MRID: 469044-81, DACO: 6.3
1314229	2006, Independent laboratory validation of BCS analytical method 00969 for the determination of residues of BYI08330-enol in materials of animal origin, P613060584 (and Report No. P/B 964 G), DACO: 7.2.1,7.2.4
1314230	2006, Independent laboratory validation of BCS analytical method 00888 for the determination of residues of BYI08330 and BYI08330-enol in plant material, P612060583 (and Study No. P 965 G), DACO: 7.2.1,7.2.4
1314288	2006, Metabolism of [azaspirodecenyl-3-14C]BYI 08330 in the laying hen, MEF-05/273 (and Study No. M81819135), MRID: 469044-83, DACO: 6.2
1314289	2006, [Azaspirodecenyl-3-14C]BYI 08330: Absorption, distribution, excretion, and metabolism in the lactating goat, MEF-05/293 (and Study No. M31819130), MRID: 469044-82, DACO: 6.2
1314290	2006, Metabolism of [azaspirodecenyl-3-14C]BYI 08330 in potatoes, MEF-05/320 (and Study No. M1731386-9), MRID: 469044-84, DACO: 6.3
1314293	2006, Metabolism of [azaspirodecenyl-3-14C]BYI 08330 in cotton after spray application, MEF-236/04 (and Study No. M1731275-6), MRID: 469044-79, DACO: 6.3
1314288	2006, Metabolism of [azaspirodecenyl-3-14C]BYI 08330 in the laying hen, MEF-05/273 (and Study No. M81819135), MRID: 469044-83, DACO: 6.2
1314289	2006, [Azaspirodecenyl-3-14C]BYI 08330: Absorption, distribution, excretion, and metabolism in the lactating goat, MEF-05/293 (and Study No. M31819130), MRID: 469044-82, DACO: 6.2
1314290	2006, Metabolism of [azaspirodecenyl-3-14C]BYI 08330 in potatoes, MEF-05/320 (and Study No. M1731386-9), MRID: 469044-84, DACO: 6.3
1314293	2006, Metabolism of [azaspirodecenyl-3-14C]BYI 08330 in cotton after spray application, MEF-236/04 (and Study No. M1731275-6), MRID: 469044-79, DACO: 6.3
1314310	2005, [Azaspirodecenyl-2-14C]BYI08330: Extraction efficiency testing of the residue method for the determination of BYI08330, BYI08330-enol, BYI08330-ketohydroxy, BYI08330-monohydroxy and BYI08330-enol glucoside in cotton gin trash, in apple fruit and in lettuce using aged radioactive residues, DACO: 7.2.1, 7.2.4
1314313	2005, Metabolism of (azaspirodecenyl-3-14C)BYI08330 in apple after spray application, MEF-028/04 (and Study No. M1731298-1), MRID: 469044-80, DACO: 6.3

PMRA Document Number	Reference
1314326	2006, Analytical method 00966 for the determination of residues of BYI 08330, BYI08330-enol, and BYI08330-enol-GA in/on matrices of animal origin by HPLC-MS/MS, MR-150/05 (Method No. 00966), MRID: 469044-92, DACO: 7.2.1,8.2.2.4
1314349	2006, Storage stability of BYI 08330 residues in plant matrices of rotational crops, MEF-06/155 (Study No. M9991559-7), MRID: 469044-97, DACO: 7.3
1314377	2006, Analytical method 00929 for the determination of residues of BYI08330-ketohydroxy-alcohol, BYI08330-desmethyl-ketohydroxy and BYI08330-desmethyl-di-hydroxy in/on plant material by HPLC-MS/MS, MR-026105 (Method No. 00929), MRID: 469044-94, DACO 7.2.1
1314401	2006, Analytical method 00969 for the determination of residues of BYI08330-enol in/on matrices of animal origin by HPLC-MS/MS, MR-160/05 (Method No. 00969), DACO: 7.2.1,7.2.4
1314443	2006, BYI08330 - request for waiver of the requirements for poultry feeding study and analytical method for the determination of BYI08330 residues in poultry meat and eggs, RAFNPO11, MRID: 469044-91, DACO: 7.5,7.6
1314445	2006, BYI08330 150 OD - Magnitude of the residue on potato processed commodities, RAFNY020, MRID: 469045-24, DACO: 7.4.5
1314446	2006, BYI08330 150 OD - Magnitude of the residue on apple processed commodities, RAFNY014, MRID: 469045-20, DACO: 7.4.5
1314447	2006, BYI08330 150 OD - Magnitude of the residue lactating cows, RAFNX014, MRID: 469045-01, DACO: 7.5,7.6
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1314451	2006, BYI08330 150 OD and BYI08330 240 SC - Magnitude of the residue on potato, RAFNY028, MRID: 469045-19, DACO: 7.4.1,7.4.2,7.4.6
1314452	2006, BYI08330 100 OD - Magnitude of the residue on tomato processed commodities, RAFNY013, MRID: 469045-12, DACO: 7.4.5
1314485	2006, BYI08330 150 OD and BYI08330 240 SC - Magnitude of the residue on stone fruit (crop group 12 - including residue reduction samples), RAFNY001, MRID: 469045-13, DACO: 7.4.1,7.4.2,7.4.6
1314487	2006, BYI08330 150 OD and BYI08330 240 SC - Magnitude of the residue in/on leafy vegetables, RAFNY002, MRID: 469045-08, DACO: 7.4.1,7.4.2,7.4.6
1314488	2006, BYI08330 150 OD and BYI08330 240 SC - Magnitude of the residue in/on brassica leafy vegetables (crop subgroup 5A, head and stem brassica, and 5B, leafy brassica greens) including residue reduction information, RAFNY003, MRID: 469045-09, DACO: 7.4.1
1314489	2006, BYI08330 150 OD and BYI08330 240 SC - Magnitude of the residue in/on curcubit vegetables (crop group 9, including residue reduction information), RAFNY007, MRID: 469045-11, DACO: 7.4.1,7.4.2,7.4.6

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1314490	2006, BYI08330 150 OD and BYI08330 240 SC - Magnitude of the residue on citrus (crop group 10, citrus fruits; includes residue reduction samples), RAFNY008, MRID: 469045-14, DACO: 7.4.1,7.4.2,7.4.6
1314492	2006, BYI08330 150 OD and BYI08330 240 SC - Magnitude of the residue on pome fruit (apple and pear), RAFNY009, MRID: 469045-15, DACO: 7.4.1,7.4.2,7.4.6
1314494	2006, BYI08330 150 OD and BYI08330 240 SC - Magnitude of the residue on hops, RAFNY022, MRID: 469045-18, DACO: 7.4.1,7.4.2,7.4.6
1314516	2006, BYI08330 150 OD and BYI08330 240 SC - Magnitude of the residue on fruiting vegetables (crop group 8 - tomato, bell pepper, non-bell pepper) (including residue reduction information), RAFNY006, MRID: 469045-10, DACO: 7.4.1,7.4.2,7.4.6
1314587	2006, BYI08330 150 OD - Magnitude of the residue on plum processed commodities, RAFNY018, MRID: 469045-23, DACO: 7.4.5
1314606	2006, FDA PAM Multiresidue method (MRM) testing for BYI08330 (Spirotetramat) and eight metabolites, RAFNP007, MRID: 469044-96, DACO: 7.2.1,7.2.4
1314608	2006, BYI08330 150 OD and BYI08330 240 SC - Magnitude of the residue in field rotational crops (limited), RAFNY019, MRID: 469045-26, DACO: 7.4.4
1314610	2006, BYI08330 150 OD - Magnitude of the residue in/on grapes processed commodities, RAFNY015, MRID: 469045-21, DACO: 7.4.5
1314614	2006, Indepedent method validation of Bayer Method No.00966 (Report No.MR-150/05) BYI08330: Analytical method 00966 for the determination of residues of BYI08330, BYI08330-enol, and BYI08330-enol-GA in/on matrices of animal origin by HPLC-MS/MS. DACO 7.2.1.
1314621	2006, BYI08330 150 OD and BYI08330 240 SC - Magnitude of the residue on tree nuts (crop group 14), RAFNY010, MRID: 469045-16, DACO: 7.4.1,7.4.2,7.4.6
1314622	2006, BYI08330 150 OD and BYI08330 240 SC - Magnitude of the residue in/on grapes, RAFNY011, MRID: 469045-17, DACO: 7.4.1,7.4.2,7.4.6
1314624	2006, Independent laboratory validation of the residue analytical method: "Analytical method 00857 for the determination of residues of BYI08330 (parent compound and total residue of BYI08330), BYI08330-enol, BYI08330-ketohydroxy, BYI08-mono-hydroxy and BYI 08330-enol-Glc metabolite in/on plant material by HPLC-MS/MS." MRID 46904489, DACO 7.2.1, 7.2.2, 7.2.3
1314662	2006, Storage stability of BYI 08330 and its metabolites BYI08330-enol, BYI08330- ketohydroxy, BYI08330-mono-hydroxy and BYI08330-enol-glucoside in/on orange (juice) and prunes (fruit) for 5 months, MR-06/076 (Study No. P642064705), MRID: 469044-97, DACO 7.3

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1314682	2005, Analytical Method 00857/M003 for the determination of residues of BYI 08330 and BYI08330-ketohydroxy metabolite in/on plant material by HPLC-MS/MS, MR-098/05 (Method No. 00857/M003), DACO: 7.2.1,8.2.2.4
1314689	2005, Supplement E001 of the analytical method 00857 for the determination of residues of BY08330(parent compound and total residue of BYI08330), BYI08330-enol, BYI08330-ketohydroxy, BYI08330-mono-hydroxy and BYI08330-enol-Glc metabolite in/on plant material HPLC-MS/MS, MR-148/04, DACO: 7.2.1,8.2.2.4
1314696	2006, [Azaspirodecenyl-3-14C] BYI 08330: Extraction efficiency testing (radiovalidation) of the residue method (00929) for the determination of BYI 08330-ketohydroxy-alcohol, BYI 08330-desmethyl-ketohydroxy and BYI 08330-desmethyl-di-hydroxy residues in plant samples using aged radioactive residues, MRID 46904506, DACO 7.2.1, 7.2.2, 7.2.3
1314701	2006, Metabolism of [azaspirodecenyl-3-14C]BYI 08330 in confined rotational crops, MEF-05/288 (and Study No. M1301259-1), MRID: 469045-02, DACO: 6.3
1480166	2007, Storage stability of BYI 08330 and its metabolites BYI08330-enol, BYI08330-ketohydroxy, BYI08330-mono-hydroxy and BYI08330-enol-glucoside in/on tomato (fruit), tomato (paste), potato (tuber), lettuce (head), climbing French bean (bean with pod), and almond (nutmeat) for 24 months, MRID 47244601, DACO 7.3
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1314453	2006, Determination of Dislodgeable Foliar Residue on Grapes and Hops Treated with BYI08330 150 OD, M-277037-01-1, DACO 5.9
1314646	Data Evaluation Record Spirotetramat/392201, Study Type: IN VIVO DERMAL PENETRATION STUDY–RAT, USEPA, SA06009, MRID 46904563, DACO 5.8

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1314255	2005, BYI08330[azaspirodecenyl-3-14C]: Anaerobic aquatic metabolism, M-261943-01-1, MRID: 469044-11, DACO: 8.2.3.5.6
1314287	2005, Aerobic degradation/metabolism of BYI8330 in four different soils (Amendment No. 1), MEF-04/169 (Study No. M1251207-8), MRID: 469044-08, DACO: 8.2.3.4.2
1314304	2006, Outdoor metabolism of [azaspirodecenyl-3-14C]BYI08330 in two soils, MEF-06/041 (Study No. M1251374-3), MRID: 469044-09, DACO: 8.2.3.4.2
1314305	2006, BYI08330: Aerobic aquatic metabolism, MEF-04/511 (Study No. M1511329-2), MRID: 469044-12, DACO: 8.2.3.5.2
1314317	2005, Adsorption/desorption of BYI08330-cis-enol in five different soils (final report), IM2000 (Study No. BAY55), MRID: 469044-29, DACO: 8.2.4.2
1314324	2006, [Azaspirodecenyl-3-14C]- and [azaspirodecenyl-5-14C]-labeled BYI08330-cis-enol: Comparative aerobic soil metabolism/degradation in four soils, MEF-05/157 (Study No. M1251359-6), MRID: 469044-28, DACO: 8.2.3.4.2
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1314408	2004, [Azaspirodecenyl-3-14C]- and [azaspirodecenyl-5-14C]BYI08330: Hydrolytic degradation, MEF-04/176 (Study No. M1111348-9), MRID: 469044-05, DACO: 8.2.3.2
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1314478	2005, BYI08330: Adsorption/desorption in five soils, MEF-04/373 (Study No. M1311388-5), MRID: 469044-13, DACO: 8.2.4.2
1314479	2006, BYI08330-enol: Soil column leaching (amendment to report, amendment no.1), MEF-05/356 (Study No. M1211377-2), MRID: 469044-31, DACO: 8.2.4.3.1
1314480	2005, [Azaspirodecenyl-3-14C]- and [azaspirodecenyl-5-14C]BYI08330: Phototransformation on soil, MEF-04/481 (Study No. M1131349-2), MRID: 469045-03, DACO: 8.2.3.3.1
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1314513	2006, Terrestrial field dissipation of BYI08330 in New York soil, 2004, MEFNY004, MRID: 469044-24, DACO: 8.3.2
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1314515	2006, Partition coefficients 1-octanol / water of BYI 08330-enol (AE 1302944) at pH 5, pH 7 and pH 9 (shake flask method), PA06/036, DACO: 8.5.1
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1314660	2006, BYI 08330-cis-ketohydroxy partition coefficient 1 - Octanol / water (HPLC-method), PA05-098, DACO: 8.5.1
1314684	2006, Degradation of BYI08330 in four soils under aerobic conditions: kinetic evaluation, MEF-05/249, DACO: 8.2.3.4.2
1314692	2006, Kinetic evaluation of laboratory soil degradation studies of BYI08330-enol, BYI08330-ketohydroxy, MEF-06/199, DACO: 8.2.3.4.2
1314153	2005, Toxicity of BYI 08330 to the freshwater diatom Navicula pelliculosa, EBFNX008, MRID: 469044-53, DACO: 9.8.2
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1314203	2006, Pseudokirchneriella subcapitata - Growth inhibition test with BYI 08330 (tech.), Bayer CropScience AG, Laboratory Report No. DOM 23092, MRID: 469044-51, DACO: 9.8.2
1314204	2006, BYI 08330 techn. a.s.: 5-day-dietary LC50 bobwhite quail (Colinus virginianus), BAR/LC017, MRID: 469044-45, DACO: 9.6.2.4
1314205	2006, Acute oral toxicity for bobwhite quail (Colinus virginianus) for the test item BYI 08330 (tech.), M-115911-02-2, MRID: 469044-44, DACO: 9.6.2.1
1314260	2005, Dose-response toxicity (LR50) of BYI 08330 150 OD to the green lacewing Chrysoperla carnea (STEPH.) under extended laboratory conditions (including food-application), 05 10 48 082, DACO: 9.2.5
1314271	2006, BYI 08330 - Acute toxicity to mysids (Americamysis bahia) under flow-through conditions, EBFNX010, MRID: 469044-36, DACO: 9.4.2
1314280	2006, Lemna gibba G3 - Growth inhibition test with BYI 08330 (tech.) under static-renewal test conditions, DOM 24019, MRID: 469044-50, DACO: 9.8.5
1314303	2005, Acute toxicity of BYI 08330-enol to the waterflea Daphnia magna in a static laboratory test system -limit test, EBFNM012, MRID: 469044-74, DACO: 9.3.2
1314308	2005, Acute toxicity of BYI 08330-enol to fish (Oncorhynchus mykiss), EBFNM013, MRID: 469044-75, DACO: 9.5.3.1
1314312	2006, Acute toxicity of BYI 08330 150 OD to the honeybee Apis mellifera L. under laboratory conditions, 051048032, MRID: 469044-61, DACO: 9.2.8
1314319	2006, Acute toxicity of BYI 08330 (tech.) to fish (Cyprinus carpio), DOM24022, DACO: 9.5.2.2
1314322	2006, Assessment of side effects of BYI 08330 OD 100 on the honey bee (Apis mellifera L.) in the semi-field, 20041144/01-BZEU, MRID: 469044-59, DACO: 9.2.8
1314328	2006, Acute toxicity of BYI 08330 OD 150 to fish (Oncorhynchus mykiss) under static conditions, EBFNM008, MRID: 469044-60, DACO: 9.5.4
1314332	2006, BYI 08330-cis-ketohydroxy: Acute toxicity to earthworms (Eisenia fetida) tested in artificial soil, LKC/RG-A-47/05, MRID: 469044-72, DACO: 9.2.3.1
1314333	2005, BYI 08330-Enol: Reproduction toxicity to the earthworm Eisenida fetida in artificial soil, P18RR, DACO: 8.6
1314339	2006, 4-Methoxycyclohexanone - Acute daphnia toxicity, 2006/0032/01, DACO: 9.3.2
1314342	2006, Pseudokirchneriella subcapitata growth inhibition test with BYI 08330 OD 150, EBFNM006 (Study No. M-264263-01-2), DACO: 9.9

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1314346	2006, 4-Methoxycyclohexanone - Acute fish toxicity, 2006/0032/02, DACO: 9.9
1314347	2006, Lemna gibba G3: Growth inhibition test with BYI 08330-enol under static conditions, EBFNX065, MRID: 469044-76, DACO: 9.8.5
1314348	2005, Acute toxicity of BYI 08330-enol to larvae of Chironomus riparius in a 48 h water-only study, EBFNX073 (Study No. M-262638-01-2), DACO: 9.9
1314363	2006, Toxicity of BYI 08330 to the blue-green alga Anabaena flos-aquae, EBFNX007, MRID: 469044-52, DACO: 9.8.2
1314366	2005, Toxicity to the parasitoid wasp Aphidius rhopalosiphi (DeStephani-Perez) (Hymenoptera: Bracconidae) in the laboratory; BYI 08330 150 OD; Code: AE 1302943 00 OD15 A101, CW05/023, DACO: 9.2.6
1314368	2005, Acute toxicity of BYI 08330 technical to the sheepshead minnow (Cyprinodon variegatus) under flow-trough conditions, EBFNX006, MRID: 469044-40, DACO: 9.4.2
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1314379	2006, Toxicity of BYI 08330 technical to the saltwater diatom Skeletonema costatum, EBFNX009-1, MRID: 469044-54, DACO: 9.4.2
1314380	2006, Chironomus riparius 28-day chronic toxicity test with BYI 08330 (tech.) in a water-sediment system using spiked water, EBFN0050, MRID: 469044-43, DACO: 9.2.7
1314386	2006, Toxicity to the ladybird Coccinella septempunctata L. (Coleoptera, Coccinellidae) using an extended laboratory test including exposure to and oral uptake of BYI 08330 150 OD, CW05/053, DACO: 9.2.5
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1314457	2006, Tier I and Tier II - Vegetative vigor non-target plant study using BYI 08330 150 OD, EBFNX016, MRID: 469044-64, DACO: 9.8.4
1314471	2006, Acute toxicity of BYI 08330-ketohydroxy to larvae of Chironomus riparius in a 48 h static laboratory test system, E 322 2928-8, MRID: 469044-73, DACO: 9.3.4
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1314582	2006, Tier I seedling emergance - Non-target plant study using BYI 08330 150 OD, EBFNX017, MRID: 469044-63, DACO: 9.8.4
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